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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,561	05/26/2006	Lee R. Carlson	INST0785UTIL	9919
51017	7590	02/03/2011		
INTEL. PROP./ RND STRYKER CORPORATION 4100 EAST MILHAM AVE. KALMAZOO, MI 49001-6197			EXAMINER JANG, CHRISTIAN YONGKYUN	
			ART UNIT 3735	PAPER NUMBER
			MAIL DATE 02/03/2011	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,561	Applicant(s) CARLSON ET AL.	
	Examiner CHRISTIAN JANG	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 14-21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-27 is/are allowed.
- 6) ☒ Claim(s) 9-13 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/19/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 1-8 and 14-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 2nd, 2010.

Information Disclosure Statement

2. IDS submitted on June 6th, 2007 has been considered.

Claim Rejections - 35 USC § 112

3. Claim 13 recites the limitation "the step of diverting said continued flow of air into said isolated sample volume" in lines 2-4. There is insufficient antecedent basis for this limitation in the claim. In specifics, claim 9 recites diverting the continued flow past the isolated sample volume.

4. Claim 30 recites the limitation "the step of diverting said continued flow of gas into said isolated sample volume" in lines 2-4. There is insufficient antecedent basis for this limitation in the claim. In specifics, claim 28 recites diverting the continued air past the isolated sample volume.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

Art Unit: 3735

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 9, 10, 12, 28, and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Giron et al. (US 2005/0177056).

7. As to claims 9 and 28, Giron teaches a method of capturing and analyzing end-tidal portion of an exhalation, including the steps of drawing a flow of air/gas from the breath of a patient, respiration resulting in time-varying gas pattern (Fig. 2A - 30), monitoring the periodic element CO₂ levels of said flow of air ([0031]), identifying the transition (Fig. 5), isolating a sample volume drawn prior to said transition point ([0074]), diverting a continued flow of air past said sample volume (20), monitoring the periodic element CO₂ level of said continued flow of air to confirm said change from exhalation to inhalation ([0074]), measuring the gas level in isolated sample volume (63).

8. As to claim 10, Giron teaches the monitoring of carbon monoxide ([0020]).

9. As to claims 12 and 29, Giron teaches the step of exhausting said sample volume ([0096]).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Giron et al. (US 2005/0177056).

Art Unit: 3735

12. As to claim 11, Giron does not explicitly teach the measuring of oxygen levels in the isolated sample volumes. However, Giron teaches that the sampling mechanism could be activated based on measured oxygen levels ([0026]). As such, it would have been obvious to measure oxygen concentrations in the collected samples for obtaining additional parameters for an increase in the accuracy of patient diagnosis.

Allowable Subject Matter

13. Claims 22-27 are allowed.

14. Claims 13 and 30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter:

16. As to claims 13 and 30, the prior art of record fails to teach a step of diverting a continued flow of air/gas past said sample volume then using the continued flow of air/gas to displace the sample volume gas.

17. As to claim 22, the prior art of record fails to teach the three flow selector valves configured as claimed and the branching component as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon-Thurs (10-9:30).

Art Unit: 3735

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

CJ
/C. J./
Examiner, Art Unit 3735
1/04/10